UNITED STAT. DEPARTMENT OF COMMERCE
Pat nt and Trad mark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/894,767	02/23/98	WEITSCHIES W	SCH1526

HM12/1025

MILLEN WHITE ZELANO & BRANIGAN
ARLINGTON COURTHOUSE PLAZA I
2200 CLARENDON BOULEVARD
SUITE 1400
ARLINGTON VA 22201

EXAMINER	
DO,P	
ART UNIT	**PAPER NUMBER**
1641	13

DATE MAILED: 10/25/00

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/894,767	Weitschi s et al.
Examiner	**Group Art Unit**
Pense T. Do	1641

☒ Responsive to communication(s) filed on *Aug 4, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1, 2, 4, 5, 8-25, and 39* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 2, 4, 5, 8-25, and 39* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of group I, claims 1, 2, 4, 5, 8-25, and 39 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the four groups employ the same or corresponding special technical feature that is the use of ferrimagnetic or ferromagnetic substances as labels to detect substances either in vitro or in vivo. This is not found persuasive because this special technical feature is well known in the art. Please refer to the Japanese patent JP3220442 (filed by applicant) which teach a method of determining the concentration of antibody or antigen in a liquid sample, comprising suspending magnetic fine particles fixed with antibody or antigen binding specifically with the analyte, the antigen or antibody, in a liquid sample containing the analyte, antigen or antibody, to cause agglutination of the magnetic fine particles by antigen-antibody reaction, applying a magnetic field, and measuring the remanent magnetic flux density of the agglutinated matter to determine the particle size of the agglutinated matter.

The requirement is still deemed proper and is therefore made FINAL..

Specification

2. **Content of Specification**

(a) Title of the Invention: See 37 CAR 1.72(a). The title of the invention should be placed at the top of the first page of the specification. It should be brief but technically accurate and descriptive, preferably from two to seven words.

(b) Cross-References to Related Applications: See 37 CAR 1.78 and MEP. § 201.11.

© Statement Regarding Federally Sponsored Research and Development: See MEP. § 310.

(d) Reference to a "Microfiche Appendix": See 37CFR 1.96© and MEP. § 608.05. The total number of microfiche and the total number frames should be specified.

(e) Background of the Invention: The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(f) Brief Summary of the Invention: A brief summary or general statement of the invention as set forth in 37 CAR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(g) Brief Description of the Several Views of the Drawing(s): A reference to and brief description of the drawing(s) as set forth in 37 CAR 1.74.

(h) Detailed Description of the Invention: A description of the preferred embodiment(s) of the invention as required in 37 CAR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. This item may also be titled "Best Mode for Carrying Out the Invention." Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention

described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(I) Claim or Claims: See 37 CAR 1.75 and MEP. § 608.01(m). The claim or claims must commence on separate sheet. (37 CAR 1.52(b)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps.

(j) Abstract of the Disclosure: A brief narrative of the disclosure as a whole in a single paragraph of 250 words or less on a separate sheet following the claims.

(k) Drawings: See 37 CAR 1.81, 1.83-1.85, and MEP. § 608.02.

(l) Sequence Listing: See 37 CAR 1.821-1.825.

Please revise the specification according to the above guidelines. Also please clarify if there is no missing text on page 1A in the specification. There seems to be some missing text after the first page of the specification. Please clarify.

Claim Rejections - 35 U.S.C. § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 2, 4, 5, 8-25 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For all independent claims, please insert the article --A-- before "Process" or "Compound" in line 1.

For all dependent claims, please insert the article --The-- before "Process" or "Compound" in line 1.

Claims 1, 2, 4, 5, 8-25 and 39 lack conventional claim language, e.g. comprising, having, consisting of, etc. Please replace "characterized of" with the conventional claim language.

The process claims do not recite method steps.

Claim 4 lacks antecedent support for "the structure-specific substances". See also claim 22 for the same problem.

Claim 8 is indefinite in reciting that the sample is *moved* during measurement, e.g. from and to where the sample is being moved?

Claim 8 also lacks antecedent support for "the sample signal".

Claim 9 lacks antecedent support for magnetic field sensors and induction coils. The method of claim 1 (which claim 9 depends on) does not recite any magnetic field sensors nor the induction coils. See also claim 10 for the same deficiency.

Claim 11 is unclear as what the "step-by-step magnetization" is, e.g. what the steps?

Claims 13, 14, 15 lack antecedent support for "the Neelian relaxation times". Claim 1 does not recite any Neelian relaxation times.

Claim 24 is indefinite as what component of claim 11 the "agents" refers to, e.g. there is not any agent recited in claim 11.

Claim 25 provides for the use of the process according to claim 11 in fertility, histocompatibility, allergology, infectiology, etc., but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 25 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 39 is indefinite for not reciting the utility of the magnetite-labeled anticollagen III and SQUID(s), e.g. what are the magnetite-labeled anticollagen III and SQUID(s) being used as ?

Claim Rejections - 35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 3220442 A (TDK Corp).

TDK Corp. teaches a method of determining the concentration of antigen/antibody in a liquid sample, comprising suspending magnetic fine particles fixed with antibody/antigen binding specifically with the analyte, the antigen/antibody, in a liquid sample containing said analyte to cause agglutination of the magnetic fine particles by antigen-antibody reaction; applying a magnetic field to the suspension liquid containing the agglutinated matter to align the magnetic fine particles; stopping the magnetic field; and measuring the remanent magnetic flux density of the agglutinated matter to determine the particle size of the agglutinated matter. (See abstract).

7. Claims 19, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen et al. (EP0180384 July 1986).

Cohen et al. teach a stable magnetically responsive reagent carrier, substantially remanence-free particulate reagent carrier useful in immunoassay procedures. The particulate reagent carrier comprises particles or beads, each formed of a water-insoluble matrix, e.g. a gel, swellable in an aqueous solution having colloidally dispersed therein superparamagnetic granules. The size range of the particles is from 5 to 500 nanometers. The reagent carrier comprises a polymeric matrix, in which the magnetic substance is incorporated, is water insoluble but swellable in aqueous medium. (See pages 4-6).

8. Claims 1, 2, 4, 5, 8, 11, 12, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Josephson et al. (US 5,164,297).

Josephson et al. teach a ligand binding assay based upon measurements of relaxation rates of the solvents, which are obtained with a magnetic resonance (MR) spectrometer. It is termed a

solvent mediated relaxation assay system which is based on the observation that the enhancement of proton relaxation rates produced by a magnetic material can be modulated by the binding of various analytes to a magnetic material. Hence, the relaxation rate of the solvent can be interpreted to give information on the concentration of an analyte. The magnetic material comprises of superparamagnetic iron oxide (See col. 2, lines 36-50; col. 3, lines 5-29). Since claim 39 teaches determining the concentration of an analyte, anticollagen III, and using means such as SQUID to detect the relaxation magnetism of the analyte-analyte binding partner complex and the method of Josephson et al. teach determining the concentration of an ligand/analyte by measuring the relaxation rate of the solvent containing the analyte and the magnetic material, the method of Josephson has an inherent property of being able to determining the concentration of anticollagen III and using SQUID to measure the relaxation time.

Claim Rejections - 35 U.S.C. § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 3220442 (TDK, Corp.) further in view of Cohen et al.

TDK, Corp. has been discussed above.

However, TDK, Corp. does not teach the particle size range from 1-1000 nm or the ferromagnetic and ferrimagnetic substances are stabilized with a shell that is made of oligomeric or polymeric carbohydrates, proteins, peptides, nucleotides, surfactants, synthetic polymers and/or lipids.

Cohen et al. teach the particle size range from 5-500 nm and a polymeric matrix.

It would have been obvious to one of ordinary skill in the art to use particles of size range taught by Cohen et al. in the method of TDK, Corp. because such size range falls within the size range of colloidal particles.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

12. Claims 1, 9, 10, 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 15, 20 of U.S. Patent No. 6,027,946. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both the pending application and Patent '946 are drawn to a method for

qualitative/quantitative detection of analytes in liquid phase or solid phase, comprising labeling the analytes with stable ferromagnetic colloidal particles or ferrimagnetic colloidal particles and determining the magnetization of the labeled analytes as a quantitative or quantitative measurement of the analyte.

Allowable Subject Matter

13. Claims 13-15, 21 are allowed.

The prior arts do not teach the intrinsic Neelian relaxation times of the ferromagnetic and ferrimagnetic substances that are greater than the measuring time.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is (703) 308-4398. The examiner can normally be reached on Mon-Fri from 7 a.m. to 4 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Pensee T. Do
Patent Examiner
October 23, 2000

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600